IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

ABBOTT GMBH & CO., KG, ABBOTT BIORESEARCH CENTER, INC., ABBOTT BIOTECHNOLOGY, LTD. Plaintiffs, v. CENTOCOR ORTHO BIOTECH, INC., CENTOCOR BIOLOGICS, LLC. Defendants.	C.A. No. 4:09-CV-11340 (FDS) JURY TRIAL DEMANDED

ABBOTT'S MEMORANDUM REGARDING JURY INSTRUCTIONS

Abbott submits this memorandum with respect to issues raised at the charging conference held on September 21, 2012 and in response to Centocor's brief addressing those issues.

I. INSTRUCTION UNDER *MICROSOFT CORP. V. I4I LTD. PARTNERSHIP*

As a result of the charging conference, Abbott understands that, to the extent an instruction is given under *Microsoft Corp. v. i4i Ltd. Partnership*, 131 S. Ct. 2238 (2011), the Court intends to edit the current draft of the instruction in order to make it bilateral; that is, to also instruct the jury that where the prior art ***was*** considered by the Patent Office, the burden of proof may be harder to carry for the challenger. The remaining issues with the instruction are: (1) when is prior art "new" and "material" and (2) whether the *i4i* principle should be extended in this case to issues other than prior art.

A. Relevant Law

The relevant paragraph of *i4i* states:

> When warranted, the jury may be instructed to consider that it has heard evidence that the PTO had no opportunity to evaluate before granting the patent. When it is disputed whether the evidence presented to the jury differs from that evaluated by the PTO, the jury may be instructed to consider that question. In either case, the jury may be instructed to evaluate whether the evidence before it is ***materially new***, and if so, to consider that fact when determining whether an invalidity defense has been proved by clear and convincing evidence.

Id. at 2251 (emphasis added).

i4i makes clear that, in order for such an instruction to be given, art must not only be new, it must be "materially new." Although *i4i* does not elaborate on what it means to be "materially new," Federal Circuit law has. In order for there to be an instruction about whether the burden of proof is more or less easily carried, there must be a "showing that the uncited art is

more relevant than that cited." *Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Co.*, 730 F.2d 1452, 1460 (Fed. Cir. 1984).[1]

American Hoist addressed the same issue as *i4i*; that is, whether the burden of proof should be shifted where an infringer offers prior art that was not considered by the Patent Office. As in *i4i*, the Court held that the burden of proof did not change but that prior art not before the Patent Office could make the burden more easily met. Unlike *i4i*, however, the court expressly discussed what was necessary before such a conclusion could be reached in holding that the "touchstone" of the analysis is whether the uncited art is more relevant than the art that was considered.

> Because the mere introduction of non-considered art (a common phenomenon) does not "weaken" or otherwise affect the presumption, there is no basis for adjusting the required level of proof downward to a "mere preponderance". That the clear and convincing standard may more easily be met when such non-considered art ***is more pertinent*** than the cited art means that determination of whether the patent challenger has met its burden turns on the relationship of the uncited art to the claimed invention. . . .
>
> Because the touchstone is whether the uncited art is sufficiently more relevant than that cited to serve as evidence of obviousness, argument respecting a presumption based on the uncited art's classification is pointless. The argument here, moreover, appears to have led to the erroneous view that Lindemann bore the burden of proving that the uncited art had been considered. ***To the extent that the examiner's consideration of uncited art is material, the burden is on the challenger to show that "that prior art had not been considered."*** *Richdel Inc. v. Sunspool Corp.*, 714 F.2d 1573, 219 USPQ 8 (Fed. Cir. 1983). ***The challenger meets that particular burden by showing that the uncited art is more relevant than that cited, just as the patentee defeats the uncited art by showing that its relevancy is equal to or less than that cited.***

American Hoist, 730 F.2d at 1460 (emphases added).

[1] The *i4i* opinion is almost a complete endorsement of Federal Circuit law on this issue, and there is therefore no reason to disregard Federal Circuit precedent prior to *i4i.*

Thus, to be entitled to any instruction along the lines suggested by *i4i*, Centocor bears the twin burdens of showing (1) that the prior art was not considered by the Patent Office and (2) "that the uncited art is more relevant than that cited." *Id.*

B. Whether The Instruction Should Extend Beyond The Prior Art

Abbott has previously argued (and still believes) that the principle of *i4i* can, in the right circumstances, extend beyond the prior art. Those circumstances include a full record that would allow the jury to evaluate the *American Hoist* issue of whether the new evidence is more relevant than the old. That record does not exist.

Abbott sought to cross-examine Dr. Siegel on the specific matters considered by the Patent Office with respect to the written description and enablement issues. Abbott also sought to examine Dr. Marks on the details of what occurred in the Patent Office. In both instances, Centocor's objections were sustained, first, because Dr. Siegel had not reviewed the file history and, second, because the Court viewed the reasoning of the Patent Office as irrelevant under *i4i*. (Trial Tr. Day 5 at 123-24; Trial Tr. Day 8 at 178-79.)[2] Abbott does not seek to reargue those rulings. However, with the specific reasoning of the Patent Office unavailable to the jury, Centocor has not and cannot show that its "new" evidence relating to the written description and enablement issues is more relevant than the facts before the Patent Office relating to those issues.

Further, if a balanced instruction were to be given (*i.e.*, that the burden is easier to discharge if new evidence is before the Patent Office and harder to discharge to the extent the

[2] Attached as Exhibits A and B, respectively.

evidence is the same as that considered by the Patent Office),[3] the jury needs to know what evidence was before the Patent Office on the written description and enablement issues. During the prosecution of the '128 patent, the application's claims were rejected by the Patent Office on both enablement and written description grounds. In response to the Patent Office's rejection, Abbott expressly brought to the Patent Office's attention the specific portions of the specification that showed Abbott's entitlement to the claims – portions of the specification that Abbott has also relied on at trial.[4] If it were to be suggested to the jury that the crystal structure of J695 was unknown to the Patent Office and somehow relevant to the written description and enablement defenses, Abbott is surely entitled to tell the jury that the Patent Office expressly considered the issue of what was necessary to support the generic claims sought when it allowed the claims to issue. This is no different in principle than advising the jury that some of the prior art relied on by Centocor was also expressly considered by the Patent Office. Only this evidence would allow the jury to apply the balanced instruction which the Court has indicated it intends to give.

C. Proposed Instruction

In view of the *American Hoist* principle and consistent with the Court's statement that it intends to give a balanced instruction, Abbott proposes the following instruction:

> You have heard evidence that prior art was considered by the Patent and Trademark Office before granting the patents. You have also heard evidence that some of the prior art relied on by Centocor was not considered by the Patent Office. The clear and convincing standard may be more easily be met when the

[3] *See Sciele Pharma Inc. v. Lupin Ltd.*, 684 F.3d 1253, 1260 (Fed. Cir. 2012) ("Conversely, it may be harder to meet the clear and convincing burden when the invalidity contention is based upon the same argument on the same reference that the PTO already considered."); *Liebel-Flarsheim Co. v. Medrad, Inc.*, 481 F.3d 1371, 1381 (Fed. Cir. 2007) ("Although the burden of showing invalidity is 'especially difficult' when the prior art reference was before the examiner during prosecution, we find that Medrad has met that burden here." (quoting *Glaxo Group Ltd. v. Apotex, Inc*., 376 F.3d 1339, 1348 (Fed. Cir. 2004)); *Glaxo Group*, 376 F.3d at 1348 ("Apotex has the burden of showing invalidity by clear and convincing evidence. This burden is 'especially difficult' when, as is the present case, the infringer attempts to rely on prior art that was before the patent examiner during prosecution." (quoting *Al–Site Corp. v. VSI Int'l Inc*., 174 F.3d 1308, 1323 (Fed. Cir. 1999)) (internal citation omitted).

[4] As an example of the arguments before the Patent Office, one of the papers submitted by Abbott (marked by Centocor as Exhibit 1996) is attached as Exhibit C. The pages are out of order in the file history; however, the relevant argument extends from pages 16-21.

> prior art not considered by the Patent Office is more relevant than the considered prior art. Conversely, when the prior art relied on is the same as or no more relevant than the prior art considered by the Patent Office, the clear and convincing standard may be especially difficult to meet. Centocor bears the burden of showing that the prior art not considered is more relevant than the prior art that was considered.

Sources:

Microsoft Corp. v. i4i Limited Partnership, 131 S. Ct. 2238 (2011); *Liebel-Flarsheim Co. v. Medrad, Inc.*, 481 F.3d 1371, 1381 (Fed. Cir. 2007) ("Although the burden of showing invalidity is 'especially difficult' when the prior art reference was before the examiner during prosecution, we find that Medrad has met that burden here." (quoting *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1348 (Fed. Cir. 2004)); *Glaxo Group*, 376 F.3d at 1348 ("Apotex has the burden of showing invalidity by clear and convincing evidence. This burden is especially difficult when, as is the present case, the infringer attempts to rely on prior art that was before the patent examiner during prosecution.") (internal quotation marks and internal citation omitted); *Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Co.*, 730 F.2d 1452, 1460 (Fed. Cir. 1984) ("To the extent that the examiner's consideration of uncited art is material, the burden is on the challenger to show that that prior art had not been considered. The challenger meets that particular burden by showing that the uncited art is more relevant than that cited, just as the patentee defeats the uncited art by showing that its relevancy is equal to or less than that cited.") (internal quotation marks and citation omitted).

II. ENABLEMENT

Centocor's argument with respect to the enablement relies on *Genentech v. Novo Nordisk, A/S*, 108 F.3d 1361 (Fed. Cir. 1997) for two propositions: first, that the skill in the art can substitute for the specification with respect to the "novel aspects of the invention" and, second, "the patent must provide or describe how to obtain starting materials for the making the invention." As indicated at the charging conference, Abbott does not object to an instruction making the first point. The second point, however, is not relevant to the evidence of record.

To Abbott's knowledge, the phrase "starting materials" was not used once in the testimony at trial (other than in the context of Dr. Siegel referring to the starting material he provides to students taking his two-week laboratory course). As used in the *Genentech* case, the requirement that there be a description of "starting materials" in the specification arises when

there is no description of the invention itself. In *Genentech*, the claim at issue was a method claim which required a "starting material" to be carried out. There were no examples provided. *Genentech v. Novo Nordisk, A/S,* 108 F.3d at 1365-66 ("[N]either the specification nor the references cited by Genentech suggest a single amino acid sequence, out of the virtually infinite range of possibilities, that would yield hGH in a useful form when cleaved from the conjugate protein."). Here, the claims are to antibodies, not a method for making them. It is undisputed that there are hundreds of examples of the claimed antibodies provided, a lengthy description of how they were made, and a listing of the amino acid sequence for each of these antibodies. Here, there is no issue of providing "starting materials." Abbott's specification provides the ***finished*** materials – the amino acid sequences themselves – of the disclosed embodiments.

We have located no case suggesting that the *Genentech* principle stands for a broader proposition that starting materials must be provided for every antibody that might come within the invention. Such materials are, in fact, described in the patents' detailed description of phage libraries and their suggestion that the invention could also be practiced using transgenic mice. But given the absence of any testimony explaining what "starting materials" are or how they relate to the issues before the jury, the instruction sought by Centocor risks confusion of the jury.

III. WRITTEN DESCRIPTION REQUIREMENT

As Abbott advised the Court at the charging conference, its proposed jury instruction seeks to provide the jury with some additional guidance with respect to what it means for species to be "representative of the genus."

To the extent there is any guidance in the case law, it is found in the statement in *Carnegie Mellon Univ. v. Hoffmann-La Roche Inc.*, 541 F.3d 1115, 1124 (Fed. Cir. 2008) that the species should have sufficient variety to reflect the variation within the genus. In *Carnegie Mellon*, the claims at issue were "directed to recombinant plasmids that contain gene coding

regions for the expression of DNA polymerase I ***from any bacterial source***." 541 F.3d at 1119 (emphasis added). The claim itself identified the source from which the claimed composition was derived – i.e., "from any bacterial source." *Id.* The Federal Circuit held that the patent failed the representative species test for the written description requirement because "the polA gene varied among the numerous bacterial species" and, in the patent, there was an "absence of any polA gene sequence for any bacteria other than E. coli." *Id.* at 1126. The court applied the representative species test by reference to the "bacterial sources" of the genes because the patent claims themselves identified "bacterial sources" as a relevant aspect of the claimed genus. *Id.*

Thus, *Carnegie Mellon* suggests that the relevant features for determining variability are the features described in the claims. This is hardly surprising – almost all issues of patent law turn on how the invention is ***claimed***. *See Regents of the University of California v. Dako North America, Inc.*, No. 05-3955, 2009 WL 1083446, at *10 (N.D. Cal. Apr. 22, 2009) ("Plaintiffs are not required to describe a high number of species of the genus method because the '841 patent, and the prior art cited therein, describes little variation within ***the salient characteristics*** of that genus." (emphasis added)); *see also Capon v. Eshhar*, 418 F.3d 1349, 1359 (Fed. Cir. 2005) ("Precedent illustrates that the determination of what is needed to support generic claims to biological subject matter depends on a variety of factors, such as the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, the predictability of the aspect at issue, and other considerations ***appropriate to the subject matter***." (emphasis added)). Abbott does not seek to invade the province of the jury, but

believes it is appropriate to tell the jury something that will focus them on the genus ***as claimed***, not features that are unclaimed and irrelevant to what the invention is about.[5]

IV. SECONDARY CONSIDERATIONS

While some courts have recognized so-called simultaneous invention by different parties as potentially relevant to obviousness, it would be prejudicial to provide such an instruction in this case. First, there is no evidence of near simultaneous invention in this matter. On Saturday, September 21, Centocor advised Abbott that it is dropping its claim of anticipation with respect to three of the five claims at issue. With respect to the other two claims, Centocor apparently rests only on its incorrect view of the law of inventorship to maintain the defense. The undisputed evidence, however, shows that Abbott reduced the invention to practice as much as two years before Centocor's reduction to practice and before Centocor even began work on its IL-12 project. This is not invention "at or about the same time" as Abbott's invention.

Second, in light of the Court's motion in limine ruling forbidding Abbott from eliciting evidence of the interference, any "simultaneous invention" instruction would be particularly unfair. The jury would be given an obviousness theory based on the idea that two companies "independently" developed the invention even though (1) Centocor filed its own patent application and sought claims of equal breadth as Abbott's claims, (2) provoked an interference with Abbott arguing that it was entitled to a patent on that invention, and (3) lost both the priority contest and its claim that the invention was obvious. The probative value of simultaneous invention as a secondary consideration of obviousness is minimal at best and belied by the existence of interference proceedings intended to determine priority in the event of near simultaneous invention. *See American Hoist*, 730 F.2d at 1460 ("Because the statute, 35 U.S.C.

[5] For example, antibodies within the claimed genus might vary by molecular weight. But molecular weight has nothing to do with the claimed invention or its purpose. Accordingly, variation with respect to that feature would not be relevant to compliance with the written description requirement.

§ 135, (establishing and governing interference practice) recognizes the possibility of near simultaneous invention by two or more equally talented inventors working independently, that occurrence may or may not be an indication of obviousness when considered in light of all the circumstances."); *see also* Daralyn J. Durie and Mark A. Lemley, *A Realistic Approach to the Obviousness of Inventions*, 50 Wm. & Mary L. Rev. 989, 1005 (2008) (the Federal Circuit has been "somewhat dismissive" of the simultaneous invention by others as proof of obviousness) (citing cases). Where Centocor sought to take advantage of such an interference proceeding and lost -- and the jury has never been advised of that fact -- it would be unfair to instruct the jury as requested.

V. ANTICIPATION/PRIOR INVENTION

Presumably to preserve the record, Centocor has proposed an instruction suggesting that, when there are multiple inventors, each inventor must have contributed to the conception of the invention and that the "question of priority of joint invention must be determined from the beginning of the joint activities of the inventors." (Br. at 8.) This instruction is contrary to the Court's ruling on summary judgment and on Centocor's motion for reconsideration of the Court's summary judgment order. Specifically, in denying Centocor's motion for reconsideration, the Court held:

> In the March 9 Order, the Court concluded that questions about Friedrich's status as a joint inventor did not warrant summary judgment for Centocor on the issue of priority because other evidence suggested that Abbott actually invented specific embodiments within the scope of the claims first. With respect to the relationship between Friedrich's arrival and Abbott's invention date, the Court considered Federal Circuit precedents holding that priority as to a genus claim dates back to the invention of any species within that genus. *See In re Zletz*, 893 F.2d 319, 323 (Fed. Cir. 1989) ("Priority as to a genus may indeed be shown by prior invention of a single species . . . but the genus will not be patentable to an applicant unless he has generic support therefore."); *see also In re Stempel*, 44 C.C.P.A. 820, 826 (1957) ("[U]nder the law all the applicant can be required to show is priority with respect to so much of the claimed invention as the [prior art] reference happens to show. When he has done that he has disposed of the reference."). Because priority

> to a genus claim requires less than what is required to establish patentability, the Court concluded that "it is plausible that Abbott invented a species of pharmaceutical composition within the scope of its claims before Centocor's priority date of April 30, 1998, but nevertheless required contributions from Mr. Friedrich after that date in order to establish the patentability of Abbott's genus claims under 35 U.S.C. § 112."

(D.I. 340 at 10.) Abbott requests that the Court instruct the jury consistent with this ruling.

VI. ADDITIONAL ISSUES

At the charging conference, Centocor indicated that in closing it intended to rely on testimony from Dr. Eck that the crystal structure of J695 was "confidential" prior to this litigation. Abbott maintains its position that whether or not this crystal structure was available to the Patent Office is irrelevant to the issues before the jury. Further, Centocor should not be able to suggest that there is something improper about the J695 structure not having been publically disclosed. The crystal structure of J695 was not derived until years after the patent filing date, and there is no issue before the jury with respect to Abbott's compliance with its disclosure obligations to the jury.

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Respectfully Submitted,

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CERTIFICATE OF SERVICE

I certify that, on September 23, 2012, this document (filed through the ECF system) will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF).

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